



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Schuler et al.	Group Art Unit: 3772
Application No: 10/734,076	Examiner: Patel, Nihir B
Confirmation No: 7962	Attorney Docket No: 53286-US-CNT (NV.0130.00)
Filed: December 10, 2003	
Title: METERED DOSE INHALER WITH LOCKOUT	March 22, 2010 San Francisco, California 94107

**APPEAL BRIEF**

VIA U.S. MAIL

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Examiner:

In response to the Examiner's Final Rejection of September 24, 2009 and the Notice of Appeal filed on December 22, 2009, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby appeals to the Board of Patent Appeals and Interferences and provides this Supplemental Appeal Brief. Appellant requests the reversal of the Final Rejection.

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Date: March 22, 2010

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**(1) *Real Party in Interest***

The real party in interest of the present application is Novartis AG (by way of assignment from Novartis Pharmaceuticals AG and from Nektar Therapeutics, which was formerly Inhale Therapeutic Systems, Inc.), having a place of business at Forum 1, Novartis Campus, CH-4056 Basel, Switzerland.

**(2) *Related Appeals and Interferences***

Appellant, Appellant's legal representative, and assignee are aware of no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

**(3) *Status of Claims***

Claims 1-32 are presently pending in the case. Claims 1-32 have been finally rejected. The rejection of each of claims 1-32 is hereby appealed.

**(4) *Status of Amendments***

No amendments after Final Rejection have been filed. Accordingly, all amendments made during prosecution of the case have been entered.

**(5) Summary of the Claimed Subject Matter**

As recited in claim 1, shown in Figures 1A, 1B, 2A and 2B, and discussed on page 7 line 18 through page 8 line 26, an aerosolization device comprises: a housing (115); a container (105) comprising a reservoir (110) storing a pharmaceutical formulation which comprises a propellant; and a metering valve (125) in communication with the reservoir (110), the metering valve (115) being moveable into the container (105) to an actuated position when a user applies a force to the container to cause the container to move within the housing, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position. The device also comprises a contact member (145) in the housing (115), the contact member (145) being moveable between a first position (Figures 1A and 1B) and a second position (Figures 2A and 2B), wherein a portion of the metering valve (125) is able to contact the contact member (145) when in the first position and is unable to contact the contact member (145) when in the second position (see page 8 lines 13-26).

As recited in claim 5, shown in Figures 6A and 6B, and discussed on page 13 line 27 through page 15 line 21, an aerosolization device comprises: a housing (115); a container (105) comprising a reservoir (110) storing a pharmaceutical formulation which comprises a propellant; and a metering valve (125) in communication with the reservoir (110), the metering valve (125) being moveable into the container (110) to an actuated position when a user applies a force to the container to cause the container to move within the housing, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position. The device also comprises a contact member (145) in the housing, the contact member (145) having a first configuration (Figure 6A) and a second configuration (Figure 6B), wherein a portion of the metering valve (125) is able to contact the contact member (145) when in the first configuration in a manner which allows the metering valve (125) to be moved to the actuated position, and wherein a portion of the metering valve (125) is able to contact the contact member (145) when in the second configuration in a manner which does not

allow the metering valve (125) to be moved to the actuated position (see page 14 line 18 through page 15 line 6).

As recited in claim 10, shown in Figures 6A and 6B, and discussed on page 13 line 27 through page 15 line 21, an aerosolization device comprises: a housing (115); a container (105) comprising a reservoir (110) storing a pharmaceutical formulation which comprises a propellant; and a metering valve (125) in communication with the reservoir (110), the metering valve (125) being moveable into the container (105) to an actuated position when a user applies a force to the container to cause the container to move within the housing, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position. The device also comprises a contact member (145) in the housing (115), the contact member (145) being moveable from a first condition (Figure 6A) to a second condition (Figure 6B), wherein when the contact member (145) is in the first condition, the metering valve (125) may contact the contact member (145) so as to allow the metering valve (125) to be moved to the actuated position, and wherein a portion of the metering valve (125) is able to contact the contact member (145) when in the second condition in a manner which does not allow the metering valve (125) to be moved to the actuated position (see page 14 line 18 through page 15 line 6).

As recited in claim 18, shown in Figures 1A, 1B, 2A and 2B, and discussed on page 7 line 18 through page 8 line 26, an aerosolization device comprises: a housing (115); a container (105) comprising a reservoir (110) storing a pharmaceutical formulation which comprises a propellant; and a metering valve (125) in communication with the reservoir (110), the metering valve (125) being moveable into the container (105) to an actuated position when a user applies a force to the container to cause the container to move within the housing, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve (125) is moved to the actuated position. The device also comprises a contact member (145) in the housing (115), wherein the metering valve (125) may be moved to the actuated position when the metering valve and/or the container is able to contact the contact member (Figures

1A and 1B) and may not be actuated when the metering valve and/or the container is unable to contact the contact member (Figures 2A and 2B).

As recited in claim 20, shown in the embodiment of Figures 1A, 1B, 2A and 2B and the embodiment of Figures 6A and 6B, and discussed on page 7 line 18 through page 8 line 26 and page 13 line 27 through page 15 line 21, an aerosolization device comprises: a housing (115); a container (105) comprising a reservoir (110) storing a pharmaceutical formulation which comprises a propellant; and a metering valve (125) in communication with the reservoir (110), the metering valve (125) being moveable into the container (110) to an actuated position when a user applies a force to the container to cause the container to move within the housing, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve (125) is moved to the actuated position. The device also comprises a contact member (145) in the housing, wherein the metering valve (125) may be moved to the actuated position when the metering valve (125) and/or the container (105) is able to contact the contact member (145) in a rigid configuration (Figures 1A and 1B or Figure 6A) and may not be actuated when the metering valve (125) and/or the container (105) is unable to contact the contact member (145) in a rigid configuration (Figures 2A and 2B or Figure 6B).

As recited in claim 22, shown in Figures 1A, 1B, 2A and 2B, and discussed on page 7 line 18 through page 8 line 26, a method is provided for controlling the operation of an aerosolization device, the aerosolization device comprising a container (105) comprising a reservoir (110) storing a pharmaceutical formulation which comprises a propellant, and the aerosolization device comprising a metering valve (125) in communication with the reservoir (110), the metering valve (125) being moveable into the container (105) to an actuated position when a user applies a force to the container to cause the container to move, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position. The method comprises: positioning a contact member (145) in a first position (Figures 1A and 1B) where the contact member (145) may contact the metering valve (125) and/or the container (105) to allow the metering valve (125) to be moved to the actuated

position; and positioning the contact member (145) in a second position (Figures 2A and 2B) where the metering valve (125) may not be moved to the actuated position.

As recited in claim 26, shown in Figures 1A, 1B, 2A and 2B and Figures 6A and 6B, and discussed on page 7 line 18 through page 8 line 26 and page 13 line 27 through page 15 line 21, a method is provided for controlling the operation of an aerosolization device, the aerosolization device comprising a container (105) comprising a reservoir (110) storing a pharmaceutical formulation which comprises a propellant, and the aerosolization device comprising a metering valve (125) in communication with the reservoir (110), the metering valve (125) being moveable into the container (105) to an actuated position when a user applies a force to the container to cause the container to move, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve (125) is moved to the actuated position. The method comprises configuring a contact member (145) in a first configuration (Figure 6A) wherein the contact member (145) may contact the metering valve (125) to allow the metering valve (125) to be moved to the actuated position and configuring the contact member (145) in a second configuration (Figure 6B) wherein the metering valve (125) may contact the contact member (145) but may not be moved to the actuated position.

#### ***(6) Grounds of Rejection to be Reviewed on Appeal***

Appellant requests review of the Examiner's following grounds of rejection:

Claims 1-32 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 3,636,949 to Kropp (hereinafter Kropp).

#### ***(7) Argument***

Appellant believes each of claims 1-32 is improperly rejected and is therefore allowable for the following reasons.

The rejection under 35 U.S.C. §102(b) are improper

*Independent claim 1*

The Examiner's rejection of independent claim 1 under 35 USC §102(b) as being anticipated by Kropp is improper, and Appellant requests reversal thereof.

Kropp does not anticipate independent claim 1. For a rejection under 35 USC §102 to be proper, the reference relied upon must disclose each and every element of the claimed invention. Non-disclosure of a single element, feature or limitation of the claim negates anticipation. Kropp does not disclose each and every element claimed and therefore does not anticipate claim 1.

Claim 1 is to an aerosolization device comprising, *inter alia*, a housing, a container, and a metering valve which is moveable into the container to an actuated position when a user applies a force to the container to cause the container to move within the housing. Kropp does not disclose a metering valve that is movable into a container when a user applied a force to the container. In addition, Kropp does not disclose a container that moves within a housing when a user applies a force to the container. Kropp teaches a breath-actuated dispenser rather than a dispenser that is actuated by a user's force that causes the container to move within a housing. As can be seen in Figure 2 of Kropp, the container (20) is constrained (see elements 15 and 16) from movement relative to the housing (12) during actuation, as discussed in column 3 lines 51-54. Since Kropp does not disclose all the features claimed, it does not anticipate claim 1.

Appellant requests reversal of the rejection of claim 1 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claims 2-4, 31 and 32 which depend from claim 1 and are not anticipated by Kropp for at least the same reasons as claim 1.

*Independent claim 5*

Independent claim 5 is also not anticipated by Kropp. Claim 5 is to an aerosolization device comprising, *inter alia*, a housing, a container, and a metering valve which is moveable into the container to an actuated position when a user applies a force to the container to cause the container to move within the housing. Kropp does not disclose this featured, as discussed above. Accordingly, Kropp does not anticipate claim 5.

Appellant requests reversal of the rejection of claim 5 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claims 6-9 which depend from claim 5 and are not anticipated by Kropp for at least the same reasons as claim 5.

*Independent claim 10*

In addition, Kropp does not anticipate independent claim 10. Claim 10 is to an aerosolization device comprising, *inter alia*, a housing, a container, and a metering valve which is moveable into the container to an actuated position when a user applies a force to the container to cause the container to move within the housing. Kropp does not disclose a device as set forth in claim 10. Kropp does not disclose a housing, a container, and a metering valve which is moveable into the container to an actuated position when a user applies a force to the container to cause the container to move within the housing. Accordingly, Kropp does not anticipate claim 10.

Appellant requests reversal of the rejection of claim 10 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claims 11-17 which depend from claim 10 and are not anticipated by Kropp for at least the same reasons as claim 10.



*Independent claim 18*

Furthermore, independent claim 18 is not anticipated by Kropp. Claim 18 is to an aerosolization device comprising, *inter alia*, a housing, a container, and a metering valve which is moveable into the container to an actuated position when a user applies a force to the container to cause the container to move within the housing. Kropp does not disclose at least this recited feature. Therefore, Kropp does not anticipate the claim.

Appellant requests reversal of the rejection of claim 18 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claim 19 which depends from claim 18 and is not anticipated by Kropp for at least the same reasons as claim 18.

*Independent claim 20*

Kropp does not anticipate independent claim 20, either. Claim 20 is to an aerosolization device comprising, *inter alia*, a housing, a container, and a metering valve which is moveable into the container to an actuated position when a user applies a force to the container to cause the container to move within the housing. Kropp does not disclose this feature, as discussed above and does not anticipate claim 20.

Appellant requests reversal of the rejection of claim 20 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claim 21 which depends from claim 20 and is not anticipated by Kropp for at least the same reasons as claim 20.

*Independent claim 22*

Kropp does not anticipate independent claim 22. Claim 22 is to a method of controlling the operation of an aerosolization device which comprises a container and a metering valve moveable into the container to an actuated position when a user applies a force to the container to cause the container to move. Kropp does not disclose the

application of a force by a user to move a metering valve to an actuated position. In addition, Kropp does not disclose movement of a container in response to a user's force. Therefore, Kropp does not anticipate claim 22.

Appellant requests reversal of the rejection of claim 22 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claims 23-25 which depend from claim 22 and are not anticipated by Kropp for at least the same reasons as claim 22.

*Independent claim 26*

Kropp does not anticipate independent claim 26. Claim 26 is to a method of controlling the operation of an aerosolization device which comprises a container and a metering valve moveable into the container to an actuated position when a user applies a force to the container to cause the container to move. Kropp does not disclose the application of a force by a user to move a metering valve to an actuated position. In addition, Kropp does not disclose movement of a container in response to a user's force. Therefore, Kropp does not anticipate claim 26.

Appellant requests reversal of the rejection of claim 26 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claims 27-30 which depend from claim 26 and are not anticipated by Kropp for at least the same reasons as claim 26.

## Conclusion

Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

JANAH & ASSOCIATES

Dated: March 22, 2010

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**(8) Claims Appendix**

1. An aerosolization device comprising:  
a housing;  
a container comprising a reservoir storing a pharmaceutical formulation which comprises a propellant;  
a metering valve in communication with the reservoir, the metering valve being moveable into the container to an actuated position when a user applies a force to the container to cause the container to move within the housing, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position; and  
a contact member in the housing, the contact member being moveable between a first position and a second position, wherein a portion of the metering valve is able to contact the contact member when in the first position and is unable to contact the contact member when in the second position.
2. An aerosolization device according to claim 1 wherein the metering valve may be moved to the actuated position only when the contact member is in the first position.
3. An aerosolization device according to claim 1 wherein the container and the metering valve are moveable within the housing and wherein when the contact member is in the first position, the metering valve is able to contact the contact member so that it may be moved into the container to the actuated position and when the contact member is in the second position, the metering valve is unable to contact the contact member and cannot be moved into the container to the actuated position.
4. An aerosolization device according to claim 1 further comprising a controller adapted to selectively control the movement of the contact member.

5. An aerosolization device comprising:
  - a housing;
  - a container comprising a reservoir storing a pharmaceutical formulation which comprises a propellant;
  - a metering valve in communication with the reservoir, the metering valve being moveable into the container to an actuated position when a user applies a force to the container to cause the container to move within the housing, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position; and
  - a contact member in the housing, the contact member having a first configuration and a second configuration, wherein a portion of the metering valve is able to contact the contact member when in the first configuration in a manner which allows the metering valve to be moved to the actuated position, and wherein a portion of the metering valve is able to contact the contact member when in the second configuration in a manner which does not allow the metering valve to be moved to the actuated position.
6. An aerosolization device according to claim 5 wherein the metering valve may be moved to the actuated position only when the contact member is in the first configuration.
7. An aerosolization device according to claim 5 wherein the container and the metering valve are moveable within the housing and wherein when the contact member is in the first configuration, the metering valve is able to contact the contact member so that it may be moved into the container to the actuated position and when the contact member is in the second position, the metering valve is able to contact the contact member but cannot be moved into the container to the actuated position.
8. An aerosolization device according to claim 5 wherein the contact member is rigid in the first configuration and is flexible in the second configuration.

9. An aerosolization device according to claim 5 further comprising a controller adapted to selectively control the configuration of the contact member.

10. An aerosolization device comprising:  
a housing;  
a container comprising a reservoir storing a pharmaceutical formulation which comprises a propellant;  
a metering valve in communication with the reservoir, the metering valve being moveable into the container to an actuated position when a user applies a force to the container to cause the container to move within the housing, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position; and  
a contact member in the housing, the contact member being moveable from a first condition to a second condition, wherein when the contact member is in the first condition, the metering valve may contact the contact member so as to allow the metering valve to be moved to the actuated position, and wherein a portion of the metering valve is able to contact the contact member when in the second condition in a manner which does not allow the metering valve to be moved to the actuated position.

11. An aerosolization device according to claim 10 wherein the first condition is a first position and wherein the second condition is a second position.

12. An aerosolization device according to claim 11 wherein first position is a position in the housing where the contact member may contact a portion of the metering valve.

13. An aerosolization device according to claim 10 wherein the first condition is a first configuration and wherein the second condition is a second configuration, and wherein the first configuration is a rigid configuration.

14. An aerosolization device according to claim 13 wherein the second configuration is a relatively flexible configuration.

15. An aerosolization device according to claim 10 wherein the metering valve may be moved to the actuated position only when the contact member is in the first condition.

16. An aerosolization device according to claim 10 wherein the container and the metering valve are moveable within the housing and wherein when the contact member is in the first condition, the metering valve is able to contact the contact member so that it may be moved into the container to the actuated position and when the contact member is in the second condition, the metering valve cannot be moved into the container to the actuated position.

17. An aerosolization device according to claim 10 further comprising a controller adapted to selectively control the condition of the contact member.

18. An aerosolization device comprising:  
a housing;  
a container comprising a reservoir storing a pharmaceutical formulation which comprises a propellant;  
a metering valve in communication with the reservoir, the metering valve being moveable into the container to an actuated position when a user applies a force to the container to cause the container to move within the housing, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position; and  
a contact member in the housing,  
wherein the metering valve may be moved to the actuated position when the metering valve and/or the container is able to contact the contact member and may not be actuated when the metering valve and/or the container is unable to contact the contact member.

19. An aerosolization device according to claim ~~17~~ 18 further comprising a controller adapted to selectively control when the metering valve may and may not be moved to the actuated position.

20. An aerosolization device comprising:  
a housing;  
a container comprising a reservoir storing a pharmaceutical formulation which comprises a propellant;  
a metering valve in communication with the reservoir, the metering valve being moveable into the container to an actuated position when a user applies a force to the container to cause the container to move within the housing, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position; and  
a contact member in the housing,  
wherein the metering valve may be moved to the actuated position when the metering valve and/or the container is able to contact the contact member in a rigid configuration and may not be actuated when the metering valve and/or the container is unable to contact the contact member in a rigid configuration.

21. An aerosolization device according to claim 20 further comprising a controller adapted to selectively control when the metering valve may and may not be moved to the actuated position.

[claims continued on next page]



22. A method of controlling the operation of an aerosolization device, the aerosolization device comprising a container comprising a reservoir storing a pharmaceutical formulation which comprises a propellant, and the aerosolization device comprising a metering valve in communication with the reservoir, the metering valve being moveable into the container to an actuated position when a user applies a force to the container to cause the container to move, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position, the method comprising:

positioning a contact member in a first position where the contact member may contact the metering valve and/or the container to allow the metering valve to be moved to the actuated position; and

positioning the contact member in a second position where the metering valve may not be moved to the actuated position.

23. A method according to claim 22 wherein the second position is a position where the contact member may not be contacted by the metering valve or the container.

24. A method according to claim 22 comprising returning the contact member to the first position after a condition is met.

25. A method according to claim 24 wherein the condition is the passage of a predetermined amount of time.

[claims continued on next page]

26. A method of controlling the operation of an aerosolization device, the aerosolization device comprising a container comprising a reservoir storing a pharmaceutical formulation which comprises a propellant, and the aerosolization device comprising a metering valve in communication with the reservoir, the metering valve being moveable into the container to an actuated position when a user applies a force to the container to cause the container to move, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position, the method comprising:

configuring a contact member in a first configuration wherein the contact member may contact the metering valve to allow the metering valve to be moved to the actuated position; and

configuring the contact member in a second configuration wherein the metering valve may contact the contact member but may not be moved to the actuated position.

27. A method according to claim 26 wherein the first configuration is a rigid configuration.

28. A method according to claim 26 wherein the second configuration is a flexible configuration.

29. A method according to claim 26 comprising returning the contact member to the first configuration after a condition is met.

30. A method according to claim 29 wherein the condition is the passage of a predetermined amount of time.

31. An aerosolization device according to claim 1 wherein the container moves within the housing when a force is applied by the user directly to a surface of the container.

32. An aerosolization device according to claim 1 wherein the container moves within the housing when a force is applied to an intermediate member.

[end claims]

**(9) Evidence Appendix**

none

**(10) Related Proceedings Appendix**

none